510(k) SUMMARY

JAN 25 2013

A. Company Information

Company Name: Codman & Shurtleff, Inc.
Address: 325 Paramount Drive
Raynham, MA 02767
Telephone: 408-433-1400
Fax: 408-433-1585
Contact Person: Richard Kimura

Date of Submission: November 16, 2012

B. Trade/Device Name:

TRUFILL® Pushable Coils and TRUFILL® DCS ORBIT™ Detachable Coil System

Common Name: Artificial Embolization Device
Classification Name: Neurovascular Embolization Device
Regulation Number: 21 CFR 882.5950
Product Code: HCG

C. Predicate Device Information:

Device	Company	510(k) Number/ Concurrence Date	Product Code	Predicate For:
Vascular Occlusion System	Codman & Shurtleff, Inc	K964367 January 30, 1997	HCG	Intended Use Design Materials Manufacturing Sterilization
Vascular Occlusion System	Codman & Shurtleff, Inc	K972881 June 4, 1998	HCG	Intended Use Design Materials Manufacturing Sterilization
Vascular Occlusion System	Codman & Shurtleff, Inc	K983483 March 24, 1999	HCG	Intended Use Design Materials Manufacturing Sterilization

Device	Company	510(k) Number/ Concurrence Date	Product Code	Predicate For:
TRUFILL DCS ORBIT Detachable Coil System	Codman & Shurtleff, Inc	K030963 June 20, 2003	HCG	Intended Use Design Materials Manufacturing Sterilization
TRUFILL DCS ORBIT Detachable Coil System	Codman & Shurtleff, Inc	K032553 September 23, 2003	HCG	Intended Use Design Materials Manufacturing Sterilization
TRUFILL DCS ORBIT Detachable Coil System	Codman & Shurtleff, Inc	K053197 December 15, 2005	HCG	Intended Use Design Materials Manufacturing Sterilization
TRUFILL DCS ORBIT Detachable Coil System	Codman & Shurtleff, Inc	K080967 May 2, 2008	HCG	Intended Use Design Materials Manufacturing Sterilization

D. Device Description:

The intent of endovascular treatment using embolic microcoils is to pack the lumen of the aneurysm with the microcoil mass, thereby eliminating the influx of blood into the aneurysm. As blood flow is disrupted within the aneurysm, intraluminal thrombosis leads to exclusion of blood flow from the parent artery into the aneurysm. Blood flow in the parent artery is then secluded from the aneurysm and the weakened wall of the aneurysm is isolated from arterial pressures. Coil embolization may also be used to treat arteriovenous malformations and fistulas by packing coils into the lumen of the parent vessel feeding into the unwanted arteriovenous structure, resulting in cessation of blood

flow. Stagnated blood within the arteriovenous malformation or fistula then thromboses, leading to involution and absorption of the aberrant vessels.

The TRUFILL Vascular Occlusion System:

The Vascular Occlusion System consists of the TRUFILL Pushable Coils and TRUPUSH Coil Pusher. The TRUFILL Pushable Coil is loaded into the proximal end of a compatible microcatheter and advanced through the catheter to the desired vessel location. The coil is deployed using the TRUPUSH Coil Pusher which is sold separately. The TRUFILL Pushable Coils are made from platinum/tungsten and synthetic fibers, and are designed for use under fluoroscopy with the TRUPUSH Coil Pusher and microcatheters having a minimum .021" I.D. (0.5 mm). The TRUFILL Pushable coils are available in straight and shaped configurations.

The TRUFILL DCS ORBIT Detachable Coil System:

The TRUFILL DCS ORBIT Detachable Coil System consists of a delivery system (delivery tube and coil introducer) and an embolic coil. The embolic coil is the implantable segment of the device, and is comprised of a vasoocclusion coil wound from a platinum alloy wire into a primary coil and then formed into a secondary helical or complex shape. The embolic coil is detached from the delivery tube via a proprietary hydraulic release mechanism using the TRUFILL DCS Syringe II which is sold separately. The TRUFILL DCS ORBIT Detachable Coil System is designed for use under fluoroscopy with compatible infusion catheters, and is available in Standard and Fill configurations.

E. Intended Use:

Pushable Coils may be used to reduce or block the rate of blood flow in vessels of the peripheral and neurovasculature. They are intended for use in the interventional radiologic management of arteriovenous malformations, arteriovenous fistulas, and other vascular lesions of the brain, spinal cord and spine.

The TRUFILL DCS ORBIT Detachable Coil System is indicated for embolizing intracranial aneurysms and other vascular malformations such as arteriovenous malformations and arteriovenous fistulae of the neurovasculature. The TRUFILL DCS

ORBIT Detachable Coil is also intended for arterial and venous embolization in the peripheral vasculature.

F. Summary of technological characteristics of the proposed to the predicate device:

The proposed TRUFILL Pushable Coils and the TRUFILL DCS ORBIT Detachable Coils are substantially equivalent to the currently cleared TRUFILL Pushable Coils and TRUFILL DCS ORBIT Detachable Coils. No new technological characteristics are being introduced with the proposed device.

The proposed TRUFILL Pushable Coils and the TRUFILL DCS ORBIT Detachable Coils have the same intended use, same operating principle, same design, manufacturing and sterilization process. All materials are the same as the currently marketed devices with the exception of the change to the coating material on the Tyvek pouch (provided by a different vendor) and one minor change to one pouch dimension (for the TRUFILL DCS ORBIT Detachable Coil only). The following Table provides an overview of the similarities and differences for both products.

Table 1: Similarities and Differences compared to Current Product

Characteristic	TRUFILL Pushable Coils	TRUFILL DCS ORBIT Detachable Coils
Intended Use	No change	No change
Operating Principle	No change	No change
Design	No change	No change
Materials	No change (except coating material on Tyvek pouch)	No change (except coating material on Tyvek pouch)
Dimensions	No change	No change (except packaging pouch)
Manufacturing Process & Locations	No change	No change
Packaging Components	No change (except coating material on Tyvek pouch)	No change (except coating material on Tyvek pouch, and pouch dimension)
Sterilization Process & Location	No change	No change
Shelf Life	No change	No change

G. Summary of Nonclinical Testing:

Codman performed non-clinical testing necessary to demonstrate substantial equivalence to the predicate devices. Bench testing demonstrated that the TRUFILL Pushable Coils and the TRUFILL DCS ORBIT Detachable Coils perform according to their description and intended use, and established the performance characteristics of the packaging modifications.

Results of verification and validation testing conducted on the TRUFILL Pushable Coils and TRUFILL DCS ORBIT Detachable Coils demonstrated that the proposed device is substantially equivalent to the predicate device and that the packaging modifications do not impact the design, safety, operation, or performance characteristics of the device.

The following tests were conducted to verify the packaging modifications for both the TRUFILL Pushable Coils and TRUFILL DCS Detachable Coils:

- Package Integrity Testing
  - Dye Leak
  - Visual Inspection
  - Seal Strength
- Biocompatibility Testing
  - Cytotoxicity Testing
- Sterilization Verification Testing
  - EO/ECH Residuals Testing
- Packaging Shelf Life Verification
  - Dye Leak
  - Visual Inspection
  - Seal Strength

Based upon the design, materials, function, intended use, comparison with currently marketed devices and the non-clinical testing performed by Codman & Shurtleff, Inc., it

is concluded that the TRUFILL Pushable Coils and the TRUFILL DCS ORBIT Detachable Coils are substantially equivalent to the currently cleared TRUFILL Pushable Coils and the TRUFILL DCS ORBIT Detachable Coils and, therefore, do not raise any new questions of safety or effectiveness.

H. Summary of Clinical Testing:

Since there are no changes proposed to the intended use, design, performance characteristics, manufacturing process, sterilization, or principles of operation of the devices, clinical testing was not required to establish substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 25, 2013

Codman & Shurtleff, Inc.
c/o Richard K. Kimura
Regulatory Affairs Specialist
325 Paramount Drive
Raynham, MA 02767-0350

Re: K123560
Trade/Device Name: TRUFILL Pushable Coils
TRUFILL DCS ORBIT Detachable Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular Embolization Device
Regulatory Class: Class II
Product Code: HCG
Dated: December 21, 2012
Received: December 26, 2012

Dear Mr. Kimura:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above, and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K123560

Device Name: TRUFILL Pushable Coils
TRUFILL DCS ORBIT Detachable Coil System

Indications For Use:

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Prescription Use X AND/OR Over-The-Counter Use

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joyce M. Whang

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number
K123560